

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD,
INC., POLYPROPYLENE HERNIA
MESH PRODUCTS LIABILITY
LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
Stinson v. Davol, Inc., et al.
Case No. 2:18-cv-01022

DISCOVERY ORDER

Before the Court is Defendants' Motion for a Protective Order Quashing Plaintiff's Notice to Take 30(b)(6) Deposition of Defendants' Representative on Topics Relating to 2011 Line Fire and Request for Documents ([ECF No. 221](#)). Plaintiff opposes Defendants' Motion. ([ECF No. 233](#).) For the reasons that follow, Defendants' Motion is **GRANTED**.

I. Background¹

Plaintiff's case is the third bellwether trial selected from thousands of cases in this multidistrict litigation ("MDL") against Defendants. The Judicial Panel on Multidistrict Litigation described the cases in this MDL as "shar[ing] common factual questions arising out of allegations that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections." (No. 2:18-md-02846, [ECF No. 1 at PageID #1-2](#).)

¹ For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order in this case. (Dispositive Motions Order ("DMO") No. 7, [ECF No. 225](#).) All docket citations are to the *Stinson* case, 2:18-cv-1022, unless otherwise noted.

The relevant facts here are that in 2015 Plaintiff underwent a right inguinal hernia repair with an Extra-Large PerFix Plug mesh, a product manufactured by Defendants. In 2017, Plaintiff underwent exploratory surgery to determine if he had a recurrent hernia or nerve entrapment because of chronic pain in his right groin area. The explanting surgeon, Dr. Radke, noted extensive scarring and found “a large ball approximately 2.5 cm in diameter of rolled up mesh next to the pubic tubercle.” ([ECF No. 89-22 at PageID #1134.](#)) Dr. Radke removed the mesh, which he described as “slow going and extremely difficult” because of the significant scarring. (*Id.*) Dr. Radke then repaired the hernia with another of Defendants’ products, Bard Marlex Mesh. (*Id.*) After the explant surgery, Plaintiff claims to have continuing chronic pain and other complications.

The crux of Plaintiff’s claims is that Defendants knew of certain risks presented by the PerFix Plug device but marketed and sold the device despite these risks and without appropriate warnings, causing Plaintiff’s injuries. Plaintiff alleges that the polypropylene in the PerFix Plug degrades after implantation, which enhances the chronic inflammatory response in the body. ([ECF No. 124 at PageID #4826.](#)) Plaintiff also claims that the inflammation and resulting fibrosis are exacerbated by the PerFix Plug’s shape, weight, and pore size. Plaintiff also claims that the PerFix Plug is susceptible to migration and has a high incidence of chronic pain. (*Id.*) According to Plaintiff, Defendants downplayed the rate and severity of complications caused by the PerFix Plug, even when faced with reports of negative outcomes, which created an unreasonable risk of significant and permanent harm to patients. (*Id.*) Plaintiff brings this action to recover for injuries sustained as a result of the implantation of the PerFix Plug, alleging that Defendants knew of the risks presented by the device but marketed and sold it despite these risks and without appropriate warnings.

II. Legal Standard

Rule 26(b)(1) of the Federal Rules of Civil Procedure governs the scope of discovery:

Unless otherwise limited by court order, the scope of discovery is as follows: Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.

Fed. R. Civ. P. 26(b)(1). “Determining the proper scope of discovery falls within the broad discretion of the trial court.” *Gruenbaum v. Werner Enter., Inc.*, 270 F.R.D. 298, 302 (S.D. Ohio 2010) (citing *Lewis v. ACB Business Servs., Inc.*, 135 F.3d 389, 402 (6th Cir. 1998)). “An order denying further discovery will be grounds for reversal only if it was an abuse of discretion resulting in substantial prejudice.” *Lewis*, 135 F.3d at 402 (internal quotation omitted). A court must limit discovery otherwise permitted by Rule 26 if it determines that:

- (i) The discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive;
- (ii) The party seeking discovery has had ample opportunity to obtain the information by discovery in the action; or
- (iii) The proposed discovery is outside the scope permitted by Rule 26(b)(1).

Fed. R. Civ. P. 26(b)(2)(C). “[D]iscovery, like all matters of procedure, has ultimate and necessary boundaries.” *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351–52 (1978) (internal citations omitted).

III. Analysis

Plaintiff has served Defendants with a Rule 30(b)(6) Notice of Deposition and Request for Documents related to a “line fire that took place at the manufacturing facility in Puerto Rico where Plaintiff’s PerFix Plug was manufactured as well as the quality system and quality controls in place

at the time of this fire and the manufacture of Plaintiff's PerFix Plug." ([ECF No. 233 at PageID #9218](#).) Defendants have moved for a protective order quashing Plaintiff's 30(b)(6) Notice and Request for Documents and argue that the line fire is irrelevant to Plaintiff's claims, and that the proposed discovery is "overbroad, unduly burdensome, and out of proportion to the needs of this case, especially at this late stage." ([ECF No. 221 at PageID #8843](#).)

At issue is a March 2011 "line fire" at Defendants' Puerto Rico manufacturing facility. ([ECF No. 221 at PageID #8846–48](#).) The line fire, caused by an electrical issue, occurred in a "chiller" in Controlled Environment #2. ([ECF No. 218-5 at PageID #8794](#).) A chiller is "a machine that maintains relatively small amounts of components at a cool temperature while they await use on the manufacturing floor or 'line.'" ([ECF No. 221 at PageID #8845](#).) Lot 43-025999-1 consisted of 50 pounds of polypropylene monofilament RM1100262. ([ECF No. 233-1 at PageID #9239](#).) According to Defendants, Lot 43-025999-1 was used over the course of several years and was stored at a warehouse until some of the monofilament was needed for manufacturing, and at such point the required quantity of RM1100262 from Lot 43-025999-1 would be removed from the warehouse and placed in the chiller at the manufacturing facility. ([ECF No. 221 at PageID #8847](#).)

Some materials were affected by the line fire, including 1.75 pounds of RM1100262 polypropylene monofilament from Lot 43-025999-1 which had been moved into the chiller. ([ECF No. 218-5 at PageID #8800](#).) A Material Review Report ("MRR") related to the line fire was produced. (*Id.* at [PageID #8793–96](#).) Based on the investigation into the fire, "the affected materials [were to] be scrapped since possible contamination could compromise the product quality." (*Id.* at [PageID #8795](#).) The affected inventory, including the 1.75 pounds of RM1100262, Lot 43-025999-1, was disposed of in 2011. (*Id.* at [PageID #8800](#).) According to

Defendants, the rest of RM1100262, Lot 43-025999-1, including the 0.0272-pound quantity that was used in the lot for Plaintiff's device, remained in the warehouse and was not affected by the fire. ([ECF No. 221 at PageID #8847.](#)) The Inventory Disposal Authorization, which stated that the affected materials were disposed of, was signed by a quality engineer and several management level employees. ([ECF No. 218-5 at PageID #8800.](#)) The final assembly for Plaintiff's PerFix Plug was performed at the same Puerto Rico facility in January of 2015, nearly four years after the line fire. ([ECF No. 221-1 at PageID #8904.](#)) Approximately 0.0272 pounds of the RM1100262, Lot 43-025999-1 monofilament was used in the "sew plug" step of the manufacturing process for the lot of Plaintiff's device. (*Id.* at [PageID #8944.](#)) None of this material was in the chiller during the line fire. ([ECF No. 221 at PageID #8852.](#))

According to Plaintiff, Defendants have not provided credible documentation to support the assertions in their motion to quash, and that it "is still unclear whether all or part of the lot was actually scrapped." ([ECF No. 233 at PageID #9218, 9220.](#)) Additionally, the documents Defendants have provided are "ambiguous, inconsistent, and deficient." (*Id.*) Plaintiff therefore seeks to depose "someone with personal knowledge of the line fire incident, the receipt, use, handling, storage, distribution, and disposition of the polypropylene component material referenced in [Plaintiff's] Complaint and the [MRR], and the relevant quality control policies/procedures in place during this time." (*Id.*)

Defendants first argue that Plaintiff's request is untimely. The deadline for general fact discovery for bellwether trial cases in this MDL was December 2, 2019. (Case No. 18-md-2846, [ECF No. 217 at PageID #2756.](#)) According to Defendants, they produced information regarding the line fire in April of 2019 and produced the same complaint file again in September 2019 and October 2019, yet Plaintiff did not raise the issue of additional discovery related to the line fire

until September 30, 2022. ([ECF No. 221 at PageID #8850–51.](#)) Plaintiff’s reasoning for this delay is that “in 60 million pages [of discovery produced before the deadline], there was one line in the Stinson Complaint Record Detail Report that briefly mentions a fire in the Davol line, without any explanation or additional information for the PSC to make sense of this statement.” ([ECF No. 233 at PageID #9217.](#)) In reply, Defendants point out the following:

However, Plaintiff fails to acknowledge that unlike the general discovery, the documents at issue here were part of a plaintiff-specific production and bear the “Stinson” Bates label, as opposed to the “MPPE” identifier used for the broader production. Additionally, the documents at issue were provided to Plaintiff—as opposed to all plaintiffs—in a different manner that highlighted them. On April 25, 2019, Bard served the DFS and supporting documents to Plaintiff’s counsel by email. Responses to the “Plaintiff-Specific and Device Manufacturing Information” section of the DFS included a reference to a forty-five page Complaint File created in response to Plaintiff’s lawsuit. DFS at 5-6. On page 15 of that Complaint File (and of the corresponding production), was a description of the review of the Design History Record as part of the investigation of the complaint. This included the statement, “The component RM1100262 (6.3 MIL Polypropylene) lot 43-025999-1 . . . had the MRR4575 for material exposed during fire in Davol line; it was determined that had no impact on end use.” DFS at Stinson-00015 (emphasis added). The next page, in the Manufacturing Review Summary section, included the statement, “There were no manufacturing abnormalities that may have contributed to this complaint.” DFS at Stinson-00016. Instead of a “needle in the haystack,” this is the equivalent of shining a spotlight on the issue.

([ECF No. 235 at PageID #9272.](#)) Plaintiff does not dispute that Defendants produced not once, but three separate times before the discovery deadline, the Complaint file that noted the line fire. Plaintiff also does not address that Defendants twice produced the complaint file as part of plaintiff-specific production, and that the reference to the line fire was on page 15 of that production. Plaintiff instead focuses on the general MDL discovery and claims the document was a “needle in a haystack” of “approximately 60 million pages.” ([ECF No. 233 at PageID #9217.](#)) As Defendants point out, “[t]he documents that reference the line fire are limited plaintiff-specific documents that were *emailed directly to* Plaintiff’s counsel not once, but twice, in 2019, and are precisely the type of documents one would look at in order to evaluate a case-specific

manufacturing defect claim.” ([ECF No. 235 at PageID #9271](#) (emphasis in original).) Plaintiff offers no persuasive rebuttal.

Defendants next argue that the line fire had no impact on the manufacture of Plaintiff’s PerFix Plug and the discovery request is therefore irrelevant and overly broad. According to Defendants, the material affected by the 2011 fire was disposed of and was not used in the manufacture of any device, including Plaintiff’s. ([ECF No. 221 at PageID #8852](#).) As part of their Second Supplemental Defendant Fact Sheet provided on October 24, 2022, Defendants produced the MRR for the line fire with the appended Inventory Disposal Authorization. ([ECF No. 218-5 at PageID #8792–8804](#).) Defendants have produced signed documentation that the materials affected by the line fire, which occurred four years prior to the manufacture of Plaintiff’s PerFix Plug, were disposed of and were therefore not used in the manufacture of any devices. As the Court noted above, the Inventory Disposal Authorization indicated that the affected materials, including the 1.75 pounds of RM1100262, Lot 43-025999-1, were disposed of in 2011. (*Id.* at [PageID #8800](#).) The Inventory Disposal Authorization was signed by a quality engineer and several management level employees. (*Id.*) Both the Inventory Disposal Authorization and the MRR contain an inventory of the affected materials, and the MRR also indicates that affected materials were identified with a “QC Reject label.” ([ECF No. 218-5 at PageID #8795](#).)

However, Plaintiff argues that the documentation provided by Defendants is not enough, and that he “must take the deposition of someone with personal knowledge of the line fire incident, the receipt, use, handling, storage, distribution, and disposition of the polypropylene component material referenced in Stinson’s Complaint and the [MRR], and the relevant quality control policies/procedures in place during this time.” ([ECF No. 233 at PageID #9218](#).) According to Plaintiff, the signed Inventory Disposal Authorization attesting that the affected materials were

disposed of is insufficient and he needs extensive information regarding, among other things, material storage locations and methods, protocols regarding the chiller, the location of work logs and work orders, and how much of the monofilament was located somewhere other than the chiller at the time of the line fire. (*Id.* at [PageID #9225–26.](#))

The court must limit discovery if it “can be obtained from some other source that is more convenient, less burdensome, or less expensive,” or if “the party seeking discovery has had ample opportunity to obtain the information by discovery in the action.” [Fed. R. Civ. P. 26\(b\)\(2\)\(C\)\(i\) & \(ii\)](#). Both limitations apply here. Defendants have acquiesced that “[t]o the extent Plaintiff contends that he is entitled to seek additional information to confirm that the material used in the manufacture of his PerFix Plug was not exposed to the line fire, [Defendants] can provide such information through less burdensome means, including responses to interrogatories, and providing a declaration, if necessary.” ([ECF No. 221 at PageID #8857.](#)) Therefore, the information sought by Plaintiff can be obtained in a way that is more convenient, less burdensome, and less expensive. Additionally, Plaintiff has had ample opportunity to obtain the information by discovery given the fact that the Complaint File was provided three times in 2019. Further, the line fire occurred in 2011; Plaintiff’s PerFix Plug was manufactured and implanted four years later. Defendants have offered to respond, under oath, that the inventory affected by the fire was disposed of and was not included in the device implanted in Plaintiff. All of this is in addition to the untimeliness issues previously addressed. Therefore, Defendants’ Motion ([ECF No. 221](#)) is **GRANTED**.

IV. Conclusion

For the reasons set forth above, Defendants’ Motion for a Protective Order Quashing Plaintiff’s Notice to Take 30(b)(6) Deposition of Defendants’ Representative and Request for

Documents ([ECF No. 221](#)) is **GRANTED**.

IT IS SO ORDERED.

4/11/2023
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE